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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/822,080	03/30/2001	C. Neal Stewart	19603/2420 (CRF D-2354)	8901

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/822,080

Applicant(s)

STEWART ET AL.

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 09/29/03 in reply to the Office action mailed 03/27/03 has been entered. Claims 1-28 are pending in this application. Claims 1-20 are under consideration.

This application contains claims 21-28 drawn to an invention nonelected with traverse in the response of 01/07/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

All previous rejections and objections not set forth below have been withdrawn.

The Declaration of Neal Stewart under 37 CFR 1.132 filed 09/29/03 has been considered. The Declaration is not persuasive regarding 112, 1st paragraph rejections because the evidence presented is not commensurate with claim scope.

Claim Rejections - 35 USC § 112

1. Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to SEQ ID NO:1 encoding SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record as set forth in the last Office action. Applicant's arguments and the Declaration of Neal Stewart

under 37 CFR 1.132 filed 09/29/03 have been considered, but are not deemed persuasive.

Applicant's arguments are basically: given the well characterized chemical and structural profiles of the kunitz-type serine proteinase inhibitors, given the proteinase inhibitors of *Brassica oleracea* that exist in gene family, and given the teachings in this application on isolation, characterization of pl gene and its protein from cabbage as well as transformation of plants with said gene; one skilled in the art would be able to obtain serine proteinase inhibitor nucleic acid molecules other than SEQ ID NO:1 from *Brassica oleracea*, and use such nucleic acid molecules to confer insect resistance to plants. Applicant also argues nucleic acid molecules that hybridize to SEQ ID NO:1 under high stringent conditions are expected to encode functional serine proteinase inhibitor (response, pages 7- 9).

Contrary to Applicant's arguments claims drawn to nucleic acid molecules encoding kunitz-type serine proteinase inhibitor *Brassica oleracea*, and nucleic acid molecules that hybridize to SEQ ID NO: 1 under the hybridization conditions set forth in the claims, and encoding kunitz-type serine proteinase inhibitor are not supported by an enabling disclosure. On page 1 of the response and in the specification, Applicant states that PIs in cabbage are linked to plant development. Applicant also states that PI of cabbage exists in a gene family. Because PIs in cabbage are linked to plant development and exists in a gene family, variations in structure and function are expected among various serine proteinase inhibitor genes from cabbage. Significant guidance is required with regard to specific primers/probes, hybridization/wash

conditions and/or PCR conditions that will allow specific isolation of the target genes. Applicant has characterized and isolated a single BOPI gene/protein (Examples 1 and 4-5). Applicant has provided no guidance with respect to what hybridization/wash conditions or PCR reactions would allow specific isolation of additional structurally and functionally related genes. In the absence of such guidance, undue trial and error experimentation would be required to screen through the vast number of cDNA and genomic clones from cabbage, to identify those that are functionally related to SEQ ID NO: 1. Note, the hybridization conditions set forth in the claims do not define high stringency because no wash conditions are specified, and therefore, are not expected to yield nucleic acid molecules that are functionally related to SEQ ID NO: 1.

In Genentech Inc v. Novo Nordisk A/S (42 USPQ2d 1001 at p. 1005). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention...". . See also *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it states " the scope of enablement must only bear a "reasonable correlation" to the scope of the claims.

Written Description

Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the Office action mailed 03/27/03. Applicant's arguments addressed the rejection to nucleic acid molecule encoding kunitz type serine proteinase inhibitor from *Brassica oleracea*, but do not specifically address the rejection to hybridizing sequences.

Applicant argues that the claimed nucleic acid molecules encoding a Kuniz-type serine proteases inhibitor isolated form *Brassica oleracea* are described by specific structure and function, and therefore should meet the written description requirement. Applicant relies upon the following points to support this position: 1) the chemical and structural properties of Kunz-type serine protease are so well established, and therefore, it is not necessary to reiterate what is known in the art. 2) The Kunz-type serine protease is characterized as a family of enzymes having similar function, similar amino acid structure, and similar mechanism of inhibiting activity. 3) The *Brassica oleracea* Kunz-type proteins are characterized as having a molecular weight of about 9-25 kDa, isoelectric points from 4.5-5.0. 4). A nucleic acid molecule encoding a serine proteinase inhibitor can be used without complete understanding of its structural property. In view of the above, one skilled in the art would recognize that Applicant is in possession of the claimed invention. Applicant urges that the rejection be withdrawn.

These arguments are not persuasive. Examiner maintains that the claimed invention is not adequately described, given the lack of disclosed representative number of nucleic acid molecules encoding a kunitz-type serine proteinase inhibitor from *Brassica*

oleracea and nucleic acid molecules that hybridize to SEQ ID NO: 1 under conditions set forth in the claims. *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) where it states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. While Applicant is not required to reiterate what is known in the art, the law under 112, 1st paragraph requires that the identifying characteristics must distinguish the claimed material. A section from MPEP 2163 is repeated here "(p)ssession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)(one must define a compound by "whatever characteristics sufficiently distinguish it"). The structural properties including molecular weight of about 21,000-22,000 Daltons, two-disulfide bonds and a single reactive site for serine protease, do not distinguish the serine protease inhibitor of the invention from other Kunitz-type serine protease inhibitors. The issues of "similar inhibiting

mechanism" and therefore, the nucleic acid molecule of claim 1 is not adequately described.

With respect to the hybridizing sequences of claims 2, 9,12 and 17, it is noted that the hybridization conditions set forth in the claims do not define high stringency conditions. Therefore, one would not expect that these conditions would yield nucleic acid molecules that are structurally and functionally related to SEQ ID NO: 1.

Consequently, the disclosure of SEQ ID NO: 1 is insufficient to provide adequate written description for any and all nucleic acid molecule that hybridize to SEQ ID NO:1 under the conditions set forth in the claims. Therefore, the claimed invention lack adequate written description, as stated in the last Office action. The rejection is maintained.

Amending the claims to recite SEQ ID NO: can obviate the rejection.

Remarks

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

12/12/03

Mai



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER